K102088

OCT 20 2010

510 (K) SUMMARY

(In accordance with 21 CFR 807.92)

Submitted by: ThyssenKrupp Ceteco S.r.l.
Via S. Cannizzaro n° 2
56121 PISA (PI) - ITALY

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Date prepared: July 22nd, 2010

Trade Name: JOURNEY™; SUPRA™

Common Device Name: Inclined Platform Lift (IPL)

Predicate device: ThyssenKrupp Ceteco Inclined Platform Lift "Journey" K090856

Product description:

The Thyssenkrupp Ceteco's JOURNEY and SUPRA are unenclosed Inclined Platform Lifts (IPLs) designed to carry a wheelchair and its occupant or a mobility-impaired person seated on a folding seat between floors in a public or private facility.

They are composed of two main parts: the rail and the carriage. The rail is the part where the carriage is attached to and where it will move along. The carriage is the component where the person to be transported is positioned on.

There are currently two different models designed to address different kind of staircases.

- The JOURNEY (technically called RPSP) is designed strictly for straight stairways.
- The SUPRA, formerly JOURNEY CUBIC (technically called TP) is designed for straight and turning stairways.

Both models were included in the previous 510K submission from our Company (K090856) and were determined substantially equivalent to legally marketed predicate devices.

We are hereby providing Additional and Expanded indications, with specific reference to the Supra model.

What Supra differs from Journey in?

The two versions of the platform lift are equal for principles of operation, performances and safety devices; they differs mainly in the *rail assembly*, the *drive system* and the *power source* of the carriage.

Rail Assembly

The SUPRA rail is made of two aluminum tubes vertically spaced, while the JOURNEY rail is made of a one-piece aluminum extruded profile.

Drive System

The carriage is inserted into the rail and it moves by means of a set of wheels. The drive system consists of an electric motor and a worm gearbox that moves a pinion. The pinion engages a rack converting his rotary motion into a linear one, moving the platform up and down along the stairway.

The drive system assembly is different in that the rail assembly differs itself.

The SUPRA main carriage is composed of two cast iron trolleys with six wheels for each trolley, which support the whole load of the platform. The two trolleys of the drive system can rotate to match the stairway's angle.

The JOURNEY main carriage is composed of one carbon steel trolley, with six which support the whole load of the platform.

In both the models, the gearbox (worm gearbox), the motor, the safety brake and the limit switch are connected to the trolley. The emergency system for manual maneuvering is connected to the gearbox assembly.

Power source of the carriage

Both the platform-lifts are powered by alternating current (AC). Both the machine could be equipped with an auxiliary emergency batteries system (optional), as a back-up in case of a power outage. This optional batteries system is placed inside a cabinet in a dry and covered place, separated from the carriage and the rail.

The SUPRA is equipped by a 24V Vdc drive motor and the rail's aluminum profile contains a bus-bar that is electrically permanent connected to the main electrical box (24Vdc). The back-up batteries (option) are directly connected to the two bus-bars and provide the low voltage current to the motor.

The JOURNEY is equipped by an AC three-phase drive motors that is feed by an alternating current. The main aluminum profile contains a cable chain with its electric wire, one end is attached to the drive unit's carriage and the other end to the main switch (permanently connected). The back-up batteries (option) are connected to an inverter which increases the tension and provide a three-phase alternate current to the motor.

Product comparison Table:

	JOURNEY	SUPRA
Intended Use	To mechanically transport one person in a wheelchair or in a fold-down seat up and down stairs in a private or public facility.	
Standards compliance	ASME A17.5 Electrical Code for Elevating Devices ASME A18.1 Safety Standard for Platform Lift and Stairway Chairlift	
Type of drive unit	Rack and Pinion	
Main Power	208-240 volts AC	
Electric Motor	Yes, onboard	
Drive unit power	550 W or 750 W Vac	350 W or 700 W, 24Vdc
Electric control board	Yes	
Optional manual operation	Yes	
Key-operated Station controls	Yes	
On-Board control with Key-Switch	Yes	
Continuous pressure directional controls	Yes	
Under platform sensing to stop lift upon contact with obstacle	o Under hanger sensing to stop movement upon contact with obstacle upon being called to/from landing areas. o Multi directional ramp sensing to detect pressure from inside the platform ramps to ensure passengers positioned safely before lift begins movement. o Overspeed safety device.	
Optional fold-down seat for non-wheelchair passengers	Yes	
Automatic foldable platform	Yes	
Automatic access ramp	Yes	
Optional Battery Back-up	Yes	

Substantial Equivalence

Based on the design, performance specifications, testing, third part certification and intended use the SUPRA is substantially equivalent to the legally marketed device JOURNEY.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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% Mr. Fabrizio Fedele
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56121 PISA (PI) – Italy

OCT 20 2010

Re: K102088
Trade/Device Name: Inclined Platform-Lifts "JOURNEY" and "SUPRA"
Regulation Number: 21 CFR 890.3930
Regulation Name: Wheelchair elevator
Regulatory Class: Class II
Product Code: ING
Dated: September 13, 2010
Received: September 16, 2010

Dear Mr. Fedele:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

K102088

OCT 20 2010

510(k) Number (if known):

Device Name: Inclined Platform-Lifts "JOURNEY" and "SUPRA"

Indications for Use:

The Inclined Platform Lifts "JOURNEY" and "SUPRA" are intended to mechanically transport one person in a wheelchair or in a fold-down seat up and down stairs in a private or public facility.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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